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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

FEB 27 2013

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,291,523. The application was filed on April 27, 2011, under 35 U.S.C. § 156. Please note that patent term extension applications for U.S. Patent No. 7,115,662 for NADA 141-320 for the animal drug product ONSIOR® (robenacoxib) were filed concurrently, pursuant to the provisions of 37 C.F.R. § 1.785.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Ali Salimi at (571) 272-0909 (telephone) or (571) 273-0909 (facsimile) or by e-mail at ali.salimi@uspto.gov.

Mary C. Tilly
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Leslie Fisher
Novartis Pharmaceutical Corporation
One Health Plaza Bldg 104
East Hanover, NJ 07936

RE: ONSIOR® (robenacoxib)
Docket No. FDA-2011-E-0677